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| **A green and white sign  Description automatically generated** | **INFORMED CONSENT PROCESS****DOCUMENTATION**  |
| **Subject ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| ORA#  | Study Title: |
| Consent Version Date:  |
| Approval Date of Consent: |
| Expiration Date of Consent:  |
| Study Principal Investigator (PI): |
| Study and consent discussed with:\_\_\_ Subject \_\_\_ Legally Authorized Representative (LAR)\_\_\_ Family Members\_\_\_ Other (describe)How was Consent obtained?\_\_\_ In person\_\_\_ Telephone call\_\_\_ Online\_\_\_ Other (describe) | If not in-person, how was the subject’s identity verified?\_\_\_ Full Name (required) AND**Two** additional identifiers (minimum) \_\_\_ Date of birth\_\_\_ Last four digits of SSN\_\_\_ Address\_\_\_ Emergency Contact name\_\_\_ Other (describe) |
| Key information presented to subject first? | [ ]  YES | [ ]  NO |
| Purpose of study discussed with subject? | [ ]  YES | [ ]  NO |
| Procedures discussed with subject? | [ ]  YES | [ ]  NO |
| Risks and Benefits discussed with subject? | [ ]  YES | [ ]  NO |
| All of subject’s or LAR’s questions were answered? | [ ]  YES | [ ]  NO |
| Subject or LAR verbalized understanding of consent? | [ ]  YES | [ ]  NO |
| Subject: [ ]  Agrees to Participate [ ]  Declined Participation [ ]  Wants to meet for further discussion |
| Consent signed prior to any study related procedures? | [ ]  YES | [ ]  NO |
| A copy of the executed study consent form was given to subject. (Describe how the copy was provided to them in “Comments”) | [ ]  YES | [ ]  NO |
| Is the subject currently enrolled in any other study? | [ ]  YES  | [ ]  NO |
| Does the subject have any special needs? If Yes, describe in comments section below | [ ]  YES | [ ]  NO |
| Does the subject meet all Inclusion and no exclusion criteria at this time? | [ ]  YES | [ ]  NO |
| Comments:  |
| Signature of Person Obtaining Consent: | Date and Time:  |